Appendix B

Glossary of Terms

Acronym	Term	Definition
AE	Adverse Event	Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure regardless of whether it is considered related to the medical treatment or procedure (attribution is unrelated, unlikely, possible, probable, or definite).
	Agent	A pharmaceutical drug used individually or a combination of them that is being tested in a cancer prevention trial.
	Amendment	A change to an approved clinical protocol that significantly affects the safety of the subjects, the scope of the investigation, or the scientific quality of the study. May also include administrative or minor changes, such as changes in company personnel, spelling error, etc.
	Auditing	A review of study records reviewed previously by another site monitor who assessed whether the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's SOPs, GCPs, and the applicable regulatory requirements. See also Monitoring.
	Audit Task Manager	An appropriately qualified Westat employee, by training and experience, whose responsibilities include, but are not limited to, DCP project goal planning for onsite monitoring, supervision of staff, assignment of protocol(s) and sites to monitor, assuring compliance with specific SOPs, and assuring that onsite monitoring visits are conducted, and that site visit reports are recorded appropriately.
BGCRG		Breast and Gynecological Cancer Research Group, an organ system group within DCP.
	Biomarker	A substance sometimes found in an increased amount in the blood, other bodily fluids, or tissues and which may mean a certain type of cancer is in the body. Examples of biomarkers include CA 125 (ovarian cancer), CA 15-3 (breast cancer), CEA (ovarian, lung, breast, pancreas, gastrointestinal tract cancers), and PSA (prostate cancers).
CADRG		Chemopreventive Agent Development Research Group, an organ system group within DCP.
CB		Chemoprevention Branch

Acronym	Term	Definition
CCSA	CCS Associates	A DCP contractor who is responsible for assisting the PIO, Organ Site Research Group personnel and study staff with protocol development and management of regulatory issues.
	Clinical Investigation	Any experiment in which a drug is administered or dispensed to, or used, involving one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
	Commercial Agent	Any agent not supplied under an IND but instead, obtained from a commercial source.
CDE		A standardized vocabulary with technical specifications, used to define data elements in NCI.
CFR		The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the executive departments and the agencies of the Federal Government.
CLIENT		A desktop machine in which users can interact and run applications.
CRA		An appropriately qualified employee, by training and experience, who is responsible for assuring that clinical trials are conducted according to appropriate procedures and all applicable government regulations. The CRA is also responsible for conducting onsite visits to clinical centers to verify subject eligibility, data accuracy, and compliance with regulatory requirements.
CRF	Case Report Form	A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each clinical trial.
	Confidential Information	Any data that should not be in the public domain. This includes information that may be associated with an individual patient, the personal identification of individual patients, information about participating investigators and institutions that are not already part of the public record; information regarded as proprietary by participants in DCP supported research protocols.

Acronym	Term	Definition
CRO	Contract Research Organization	A commercial organization that assumes, as an independent contractor with a sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, site monitoring visits, statistical analysis, and preparation of reports to be submitted to the Food and Drug Administration.
	Control Group	In phase III cancer prevention clinical trial of a study agent, the group that receives either a placebo or a standard agent that is being compared to a new agent.
CSAERS		Chemoprevention Serious Adverse Event Reporting System
CTC	Common Toxicity Criteria	A descriptive terminology, which is to be utilized for adverse event reporting. A grading (severity) scale is provided for each adverse event term.
CV	Curriculum Vitae	Document that outlines a person's educational and professional work history.
DARF		Drug Accountability Report Form
	Database Administrator	A systems professional trained in database administration techniques and responsible for utilizing these techniques to manage security and performance of an Oracle database. These responsibilities include: creating and removing user accounts, developing appropriate access roles and profiles, controlling and monitoring user access, identification of security violations, backup and recovery of the database, and monitoring and optimizing performance. There will be a primary and secondary project database administrator for Oracle Clinical database on the DCP project. A corporate database administrator is responsible for establishing policies and procedures for all Oracle databases at Westat.
DCP		Division of Cancer Prevention
DESK	DCP Enterprise System Knowledgebase	The computer system knowledgebase that supports DCP data such as agents and address modules.
	Dropout	A participant who does not complete a clinical trial. Subjects may discontinue participation due to disease-related, medication-related, clinical trial-related reasons, or due to the participant's own volition.

Acronym	Term	Definition
	Drug Accountability	Maintaining current and accurate records showing the quantities of drug received, dispensed, stored at the site, and returned to the sponsor.
DSMB	Data and Safety Monitoring Board	An impartial group of researchers that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.
EC	Ethics Committee	An independent body comprised of medical professionals and nonmedical members whose responsibility is to verify the integrity of the research, and human rights of the subjects participating in a particular trial are protected, thereby providing public reassurance. See Institutional Review Boards (IRBs).
	Effectiveness	The desired measure of a drug's influence on a disease condition as proven by substantial evidence from adequate and well controlled investigations. Reasonable assurance that in a significant portion of the target population, the use of the drug will provide clinically significant results; that the drug has a beneficial therapeutic effect (how well does the treatment work from the individual patient's perspective and the impact of health care resource utilization overall).
	Efficacy	A product's ability to produce beneficial effects. (Does it do what we intended it to do, or what we are claiming it can do?)
	Evaluable Subject	A subject who meets the criteria for evaluation described in the protocol or the statistical plan. Subjects with protocol violations are not evaluable.
FDA	Food and Drug Administration	An agency of the U.S. Government which oversees the study of investigational drugs and grants marketing approval for new drugs. Regulates the drug development and clinical trials industry.
	Form FDA 1572	Statement of the investigator that outlines the responsibilities that the investigator agrees to assume in order to conduct the clinical trial.
GCP	Good Clinical Practice	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Acronym	Term	Definition
	Global Librarian	A person assigned the responsibility of internal administration and change management of the Global Library in an Oracle Clinical database. This person is also assigned the responsibility of granting and revoking access for individual users to specific protocols.
GOCRG		Gastrointestinal and Other Cancer Research Group, an organ system group in DCP.
HIPAA		Health Insurance Portability and Accountability Act
HTML	Hyper Text Markup Language	A document-layout and hyperlink-specific language. It tells the browser how to display the content of the document.
HTTP	Hyper Text Transfer Protocol	A standard through which a client browser talks to a server to load the requested document.
	Human Subject	An individual participating in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.
IB	Investigator's Brochure	A collection of data, both clinical and preclinical, known to date about the investigational drug. (Also referred to as Clinical Investigation Brochure or Investigational Drug Brochure)
	Informatics	Information science.
IC	Informed Consent	A process in which a person learns key facts about a clinical trial, including potential risks and benefits, before deciding whether or not to participate in a study. Informed consent continues throughout the trial.
ICF	Informed Consent Form	The legal written record where the subject, or his/her representative, agrees to voluntarily participate in the investigation.
	Initiation Visit	A type of site visit conducted to verify that all regulatory and other requirements are in place prior to implementing a study.
ICH	International Conference on Harmonisation	A committee of U.S., European, and Japanese members organized to develop guidelines for the conduct of clinical trials (this applies to pharmaceutical products).
IND	Investigational New Drug Application	The application filed with the FDA informing them of the sponsor's intent to begin testing a new pharmaceutical product in humans.

Acronym	Term	Definition
IRB	Institutional Review Board	A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of the study participants are protected. All clinical trials in the US must be approved by an IRB before they begin.
	Investigational Agent	An agent sponsored under an Investigational New Drug Application (IND).
	Investigator	An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the agent is administered or dispensed to a subject). In the event a team of individuals conducts an investigation, the investigator is the responsible leader of the team.
	JavaScript	Lightweight Java-based scripting language used at client web browsers to perform basic web page validation and processes.
KA	Knowledge Acquisition	The formalized process of collecting information about business organizational processes necessary for developing requirements.
	Lead Organization	The institution holding the funding agreement with the NCI, which is the institution of the Principal Investigator.
LUACG		Lung and Upper Aerodigestive Cancer Group, an organ system group within DCP.
	Marketing Application	An application for a new drug submitted under section 505(b) of the act of biologics license application for a biological product submitted under the Public Health Service Act.
	Medical Site Monitor	A medically trained DCP employee, whose responsibilities include, but are not limited to, interacting with the investigator(s) and staff at the clinical site on all clinical matters related to the study and to oversee the study from a safety standpoint.
	Monitoring	The act of overseeing the progress of a clinical trial and ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPS), GCPs, and the applicable regulatory requirements. This includes the act of reviewing and evaluating particular components at a site visit: (1) conformance to IRB and consent form requirements, (2) pharmacy and drug accountability, and (3) patient case review.

Acronym	Term	Definition
NCICB		National Cancer Center for Bioinformatics
	Oracle Clinical	A software product of the Oracle Corporation designed to meet the needs of the clinical trials industry.
	Organ System Group	A specific network of physicians, nurse specialists, and other health professionals at DCP who monitor and evaluate the scientific integrity of organ-specific diseases in contracts, grants, and other long-term projects.
	Participating Organization	Institutions who by arrangement with the NCI/DCP and the lead organization participate in a clinical trial by accruing patients.
PI	Principal Investigator	The individual responsible for the conduct of the study at the clinical center and for ensuring the safety of study participants enrolled at that site (i.e., under whose immediate direction the test agent is administered or dispensed to the study participant). If a team of individuals conducts a trial, the investigator is the responsible leader of the team.
PIMS		Protocol Information Management System
	Placebo	A chemically inert substance given in the guise of medicine for its psychologically suggestive effect; it is used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual power of a drug.
	Project Director	An appropriately qualified Westat employee, by training and experience, whose responsibilities include, but are not limited to: monitoring project budgets; allocating staff resources; complying with project goals and objectives; evaluating whether the scope of work is being met; serving as official contact for the client, collaborators, and contractors; preparing project progress reports to deliver to the client on a routine basis; and assuming final responsibility for assuring that all project work is completed accurately, on time, and within budget.
	Project Manager	An appropriately qualified Westat employee, by training or experience, whose responsibilities include, but are not limited to, project goal planning, supervision of staff, and evaluation and assessment of project activities. The project manager's responsibilities may also include conducting onsite monitoring visits.

Acronym	Term	Definition
PIO	Protocol Information Office	The central office for all protocol-related information management for DCP sponsored trials. The mission of the PIO is to coordinate all administrative aspects related to clinical trial development to assure that quality protocols are developed in the most expeditious and efficient manner possible. Towards that end, the PIO collects, processes, tracks, and monitors all protocol-related information between DCP, the study site staff, Westat, and CCS Associates.
PK	Pharmacokinetics	The study of bodily absorption, distribution, and metabolism and excretion of compounds and medicines.
	Protocol	A formal written document which states the rationale, objectives, and statistical design of a clinical research trial.
PUCRG		Prostate and Urologic Cancer Research Group, one of the DCP organ system groups.
QA	Quality Assurance	Applies to onsite and institutional systems and processes established to ensure that the trial is performed and the data is generated in compliance with GCP, SOPs, and the protocol.
QOL	Quality of Life	Description of the physical, psychological, and social dimensions of the health status of a subject.
	Randomization	A method used to prevent bias in research. People are assigned by chance, often by computer, either to receive the study agent (intervention group) or not (control group).
RDC/RDE	Remote Data Capture/ Remote Data Entry	Systems for directly entering data from investigational sites electronically rather than by the physical transfer of data on paper CRFs.
SAE	Serious Adverse Event	Any Adverse Event occurring at any dose that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Important medical events that may or may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical to surgical intervention to prevent one of the outcomes listed in this definition.

Acronym	Term	Definition
	Site Coordinator	The responsible person at the clinical site who is the primary contact at the site and ensures that the studies are conducted appropriately. Also called Study Coordinator.
	Site Monitor	A Westat employee (or an employee of a subcontractor of Westat) responsible for onsite monitoring of the conduct of a trial at each site to ensure that it is conducted according to protocol specifications, company procedures, and government requirements.
	Site Visit	Onsite investigation of the facilities and/or clinical research process at an institution conducting DCP-sponsored clinical research by DCP staff or its representatives.
SOPs	Standard Operating Procedures	Written procedures describing sponsor, CRO, site or IRB procedures, or systems governing their processes. Also: standard, detailed instructions for managing a clinical trial. SOP documents provide a general framework to provide the means of efficient implementation and performance of all the functions and activities for the trial described in the SOP.
	Sponsor	An individual company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial, but who does not actually conduct the investigation
	Study Coordinator	The responsible person at the clinical site who is the primary contact at the site and ensures that the studies are conducted appropriately.
	Subinvestigator	Individuals (research fellow, resident, associates) who assist the PI in the conduct of the clinical trial. A subinvestigator has authority delegated to him or her by the PI.
URL	Universal Resource Locator	The complete address of a resource and has everything the system needs to find a document and its server on the web.